Subpart A Subcommittee (SAS)

David Borasky and Daniel Nelson

SAS Co-Chairs

Presentation to the
Secretary's Advisory Committee on Human Research Protections (SACHRP)
July 19, 2011

Outline of Today's Presentation

- Subcommittee charge and membership
- Topics for consideration at this meeting
  - Comments to Presidential Commission for the Study of Bioethical Issues → via SOH
  - Recommendations on Regulatory Requirements for Consent Documents
- Update on ongoing work

Charge to the Subcommittee

- Review and assess
  - All provisions of Subpart A of 45 CFR 46
  - Relevant OHRP guidance documents
- Based on this review and assessment
  - Develop recommendations for consideration by SACHRP in three categories:
    - Interpretation of specific Subpart A provisions
    - Development of new or modification of existing OHRP guidance
    - Possible revisions to Subpart A

Based on memo to Subcommittee from E. Prentice, Chair of SACHRP, 1/14/05 and subsequent discussion by SACHRP

Charge to the Subcommittee

- **Goals**
  - **Enhance protection of human subjects**
  - **Reduce regulatory burdens that do not contribute to the protection of human subjects**
  - **Promote scientifically and ethically valid research**

Based on memo to Subcommittee from E. Prentice, Chair of SACHRP, 1/14/05 and subsequent discussion by SACHRP

Subpart A Subcommittee
Present Members

- Elizabeth Bankert, Dartmouth College
- Laura Beskow, Duke University
- David Borasky,* RTI International
- Bruce Gordon, University of Nebraska Medical Center
- Susan Kornetsky, Children's Hospital Boston
- Gigi McMillan, We Can Pediatric Brain Tumor Network
- Daniel Nelson,* University of North Carolina - Chapel Hill
- Susan Rose, University of Southern California
- Michele Russell-Einhorn, Dana Farber Cancer Institute
- Ada Sue Selwitz, University of Kentucky

- With welcome input from
  - SACHRP members who choose to affiliate
  - Ex officio reps of Common Rule agencies

co-chairs

Subpart A Subcommittee
Past Members

- Ricky Bluthenthal, RAND Corporation
- Gary Chadwick, University of Rochester
- Felix Gyi, Chesapeake Research Review, Inc
- Isaac Hopkins, Community Research Advocate (UMDNJ) †
- Nancy Jones, Wake Forest University → NIH
- Moira Keane, University of Minnesota
- Ernest Prentice, University of Nebraska Medical Center
- Thomas Puglisi, PriceWaterhouse Coopers → VA
- Lorna Rhodes, University of Washington
- David Strauss, New York State Psychiatric Institute

- Not shown are multiple SACHRP members who chose to affiliate with SAS while members of parent committee

Subcommittee Meetings

- Jan 18, 2005 via teleconference
- Feb 14, 2005 in Alexandria, VA
- May 20, 2005 via telecon
- July 20-21, 2005 in Alexandria, VA
- Oct 4, 2005 via telecon
- Jan 9, 2006 via telecon
- Jan 30-31, 2006 in Rockville, MD
- May 11-12, 2006 in Gaithersburg, MD
- Sept 11, 2006 via telecon
- Oct 4, 2006 via telecon
- Feb 15-16, 2007 in Arlington, VA (+ retreat)
- Mar 9, 2007 via telecon
- May 31-June 1, 2007 in Arlington, VA
- July 16, 2007 via telecon
- Aug 16-17, 2007 in Arlington, VA
- Oct 3, 2007 via telecon
- Feb 21, 2008 in Rockville, MD
- May 15-16, 2008 in Rockville, MD
- Sept 22-23, 2008 in Rockville, MD
- Jan 26-27, 2009 in Rockville, MD
- June 8 & 30, 2009 via telecon
- July 8, 2009 via telecon
- Sept 1 & 30, 2009 via telecon
- Oct 21, 2009 via telecon
- Feb 24 & 26, 2010 via telecon
- Jun 1-2, 2010 in Rockville, MD
- Jun 30, 2010 via telecon
- Sept 27, 2010 via telecon
- Jan 26-27, 2011 in Rockville, MD
- Feb 18, 2011 via telecon
- April 18, 2011 via telecon
- May 9, 2011 via telecon
- June 13-14, 2011 in Rockville, MD

Supplemented by Working Group calls and e-mails

Secretarial Letters Incorporating SAS Recommendations

- 5th SACHRP letter to Secretary Leavitt → 3/14/07
  - Recommendations approved 2005-2006
    - Continuing Review → Federal Register notice on 11/06/09
    - Expedited Review → Federal Register notice on 10/26/07
- 6th SACHRP letter to Secretary Leavitt → 6/15/07
  - Recommendations approved March 2007
    - Required Training → Federal Register notice on 07/01/08
- 7th SACHRP letter to Secretary Leavitt → 1/31/08
  - Recommendations approved March & July 2007
    - Waiver of Informed Consent
    - Minimal Risk → Analytical framework and examples
- 8th SACHRP letter to Secretary Leavitt → 9/18/08
  - Recommendations approved Oct 2007, March & July 2008
    - Exemptions
    - Alternative models of IRB review
    - IRB membership rosters
    - Waiver of documentation of informed consent
    - Institutional Officials
    - American Indians and Alaska Natives
    - (Letter also addressed disaster research, and systems-level commentary)
- 10th SACHRP letter to Secretary Sebelius →7/15/09
  - Recommendations approved March 2009
    - Designation of IRBs within FWA
- 11th SACHRP letter to Secretary Sebelius → 3/24/10
  - Reaffirmation of previous rec on required education, after public RFI
- 12th SACHRP letter to Secretary Sebelius → 1/14/11
  - Informed consent and research use of Biospecimens (FAQs)

Improving the Form and Process of Informed Consent

Informed Consent

- Previous work by SAS → approved by SACHRP
  - 2007 → Waiver of IC
  - 2008 → Waiver of documentation of IC
  - 2010 → FAQs on informed consent for research use of biospecimens
  - 2011 → Parental permission and child's assent
  - 2011 → Documentation of consent
- Current work focuses on broader sets of issues relating to IC
  - Areas where regulations may provide flexibility
  - Areas where interpretation or understanding may warrant clarification

Subpart A Subcommittee (SAS) Report and Recommendations to SACHRP

Guidance on Applying the Regulatory Requirements for Research Consent Forms: What Should and Should Not be Included?

SAS Work in Progress

- Reconsideration of the Short Form regulations at §46.117
- Application/implication of informed consent regulations in internet-based research
- Ongoing focus on shortening, clarifying and/or repackaging consent documents to facilitate participant understanding